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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,204	06/06/2001	Gordon C. Shore	50013/011002	2246

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,204

Applicant(s)

SHORE ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 16-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I (claims 1-6 and 10-15) in Paper No. 4 is acknowledged.
2. Claims 1-29 are pending, claims 7-9 and 16-29 are withdrawn from consideration as being drawn to a non-elected invention. Therefore, claims 1-6, and 10-15 are examined on the merits. Applicant has elected the species of SEQ ID No: 3 for prosecution on the merits.

Claim Rejections - 35 USC § 112

3. Claims 1-6 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1, 10 and dependent claims thereof, in the recitation of the term "substantially", it is indefinite because the term is a relative term which is open to interpretation. It is noted that the specification defines the term, however, the term must be specifically and distinctly defined.
5. Claim 3 recites the term "decrease", which is a relative term of which the metes and bounds cannot be determined. One of skill in the art would not know the actual amount of decreased apoptosis is encompassed by the claim.
6. Claims 4 and 12, in the recitation of the term "degenerative cell", it is unclear as to what kind of cell is encompassed within this term. For example, is a necrotic cell,

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which is considered a degenerative cell, encompassed within the scope of this term?

Correction or further clarification is required.

Claim Rejections - 35 USC § 112

7. Claims 3-5 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among

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the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claims of the instant invention are drawn to a polypeptide that consists essentially of a BAX ART domain, wherein said polypeptide decreases apoptosis of a cell.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that the BAX is a pro-apoptotic protein (Eskes *et al* Mol Cell Biol 2000 Feb;20(3):929-35). However, no wherein the art does it teach that BAX or any region within BAX having anti-apoptotic activity. Pg 13

The amount of direction or guidance present and the presence or absence of working examples: The examples of the instant invention are drawn to the identification of important regions within the BAX protein that are required for the activation of its pro-apoptotic activity. These working examples include the description of a BAX protein missing the ART domain, wherein the protein, termed BAX Δ ART, initiates an apoptotic event. The specification alludes to a function for a fragment that contains a BAX ART domain, wherein it is capable of inhibiting apoptosis, however, no teachings beyond the mere mention of this function is made (see page 13). This is not seen as an adequate disclosure for a protein fragment that encompasses a function of inhibiting apoptosis, because one of skill in the art has not been taught that such a fragment is capable of functioning within the limitations of the claim. Because there is no teaching in the art

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nor in the specification as to what actual effect such a peptide has on apoptosis, one of skill in the art would be forced to experiment to determine the functionality of this fragment, the amount needed to perform the claimed function, and or any necessary modifications needed to preserve the fragment from degradation.

The breadth of the claims and the quantity of experimentation needed: Therefore, because of the deficiencies in the art and disclosure concerning the role of BAX ART containing fragments in inhibiting apoptosis, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-3, 6, 10, and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Korsmeyer *et al* (U.S. Patent No. 5,691,179). Claim are drawn to a purified polypeptide or pharmaceutical composition consisting essentially of a BAX ART domain, wherein the BAX is human, rat, or mouse, wherein the peptide decrease

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apoptosis, and wherein the peptide comprises the sequence of SEQ ID No: 3.

Korsmeyer *et al* disclose a sequence which consists essentially of the BAX ART domain, wherein the sequence of BAX comprises SEQ ID No: 3, wherein the BAX is human or mouse and is capable of decreasing apoptosis.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Christopher Yaen
Art Unit 1642
January 10, 2003



ALI R. SALIMI
PRIMARY EXAMINER